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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,872	11/12/1999	KENT C. COCHRUM	44041.010400	9965

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/438,872

Applicant(s)

COCHRUM ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The amendment filed 9/2/05 is acknowledged. Claims 47-53 are being considered on the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 is vague and indefinite in the recitation of "sprayed as a layer", since the extent of the layer produced is unclear, even when reading the claims in light of the specification. For example, it cannot be determined whether the dextran forms a patch or a continuous layer. Moreover, the specification indicates that the spraying is effected by spraying a dry hemostatic polymer composition in powder form onto a surface of the matrix. This is not reflected in the product by process claim as written.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 47-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 72-84 of copending

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Application No. 10/334864 and claims 1-7, 9, 11, and claims 24-28 of copending Application No. 11/145678

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each of the applications is directed to substantially the same subject matter, i.e., a matrix coated with or comprising a cross linked polysaccharide, which can be dextran which may be covalently linked to a bandage, which can be a gauze. A sprayed coating may well be covalently linked to a substrate, in this case a gauze or cellulose bandage.

Therefore the claims are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments as they pertain to the rejection have been fully considered but they are not deemed to be persuasive.

In the absence of a terminal disclaimer, the rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson & Johnson (U.K. Patent No. 629,419) or Patel. (U.S. Patent No. 5,470,576) taken with G.B. 1454055 and Smith (U.S. Patent No. 3,671,280)

The claims are directed to a dressing comprising gauze having cross-linked dextran beads sprayed as a layer onto a surface of the gauze.

Each of Johnson & Johnson and Patel discloses a wound dressing comprising a gauze coated with a polysaccharide such as alginate (See, e.g., Johnson & Johnson, page 2, col. 1, lines 163 and col. 2, lines 92-112 or Patel, Example 3).

The references differ from the claimed invention in that the gauze does not have cross-linked dextran beads produced by spraying beads as a layer onto a surface of the gauze. However, G.B. 1454055 discloses a removable dry wound dressing comprising cross-linked dextran beads on a wound contacting surface. See, e.g., Example 5. Even though the material used is not gauze, the reference envisions using a cotton fabric (page 8, line 38) which clearly encompasses gauze. In addition, given that the removable wound dressing comprises beads that are uniformly distributed between the fibers, one of ordinary skill in the art would reasonably have expected that the beads form a layer on a wound-contacting surface of the matrix. It is noted that "a sprayed layer" need not be continuous or uniform.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

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Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

In addition, Smith adequately demonstrates that compositions composed of a gauze matrix having a coating comprising high molecular weight dextran are known in the art. See, e.g., Examples 7-9.

The molecular weight exclusion limit of at least 270,000 discussed in the British patent '055 appears to be substantially the same as claimed. (See, e.g., page 2, lines 3-9). However, even if it is not, the selection of a cross-linked dextran polymer coating for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such selection is at the essence of biotechnical engineering.

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in substituting cross-linked dextran surface coating for an alginate coating on gauze because both of these polysaccharide polymers have suitable properties for use in gauze coated bandages, such as being hemostatic and preventing adhesion.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the gauze coated with alginate as taught by Johnson & Johnson or Patel by substituting therefor a cross-linked polysaccharide such as dextran as

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taught by G.B. 1454055 for the expected benefit of obtaining a dry, removable wound dressing which is more pliable and more easily removable and which has the hemostatic properties provided by a dressing comprising a cross-linked dextran polymer as a coating.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant(s) argue(s) that there is no suggestion to combine references. However, motivation can come not only from direct teaching of the prior art, but also the nature of the problem to be solved and/or the knowledge of persons of ordinary skill in the art, *Ruiz v. A.B. Chance Co.* 357 F.3d 1270, 69 USPQ2d 1686 (2004). The cited references are in the same field of endeavor and seek to solve the same problems as the instant application and claims, and one of skill in the art is free to select components available in the prior art, *In re Winslow*, 151 USPQ 48 (CCPA, 1966). Further, the examiner recognizes that references cannot be arbitrarily combined that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references, *In re Nomiya*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. One test for combining references is what the combination of disclosures taken as a whole would suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). In this case, the references use of components known in the art, such as polysaccharides coatings comprising alginate or dextran and used for their known art specific properties, which are as hemostatic agents in different combination is considered to be obvious in the absence of evidence to the contrary.

The Smith reference is analogous art to the extent that it demonstrates that a composition comprising gauze coated with a composition comprising dextran is old and well known in the art, and it was cited for this purpose (see, e.g., Example 1). It is noted in this regard that the term "having" in the claim is interpreted as open claim language, i.e., it is interpreted as "comprising".

Note still further that, contrary to applicant's argument, it is well established that motivation for combining references need not come from the references themselves, as long as

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applicant's disclosure is not improperly used in a hindsight reconstruction of the claimed invention. See *Ex parte Levengood*, 28 USPQ2d 1300 (1993), at 1301. ("Motivation for combining the references need not be explicitly found in the references themselves. Indeed, the examiner may provide an explanation based on logic and sound scientific reasoning that will support a holding of obviousness.") (Citations omitted.)

Even though the '055 patent does not disclose gauze specifically as coated with dextran, it does teach the use of coated cotton fabric, which is generally woven, in addition to cellulose fibers or paper pulp. See, e.g., Example 5, in particular, page 8, line 38. Therefore the substitution of these materials with a cotton fabric such as gauze is clearly suggested by the teachings of the '055 reference and the Johnson & Johnson or Patel references. It is emphasized that the claims are directed to a composition rather than to a method of accelerating the coagulation of blood.

Regarding the "sprayed as a layer" aspect of the composition, this is a product-by process limitation, as noted *supra*. It cannot readily be assessed whether this product is substantially different from the product of '055, for example, and applicant has not demonstrated differences on this record with objective evidence in declaration form or in the specification as filed for the claimed composition, wherein cross-linked dextran beads have been sprayed as a layer onto a wound-contacting surface of said gauze. The only spraying in the specification is effected by spraying a dry hemostatic polymer composition in powder form onto a surface of the matrix. Specification, page 25, lines 28-30. There is no indication of whether the spraying results in a continuous or discontinuous layer, or the thickness thereof.

In response to applicant's extensive arguments regarding the unexpected hemostatic properties of the invention, it is noted that whether or not a composition comprising a paper pulp or cotton coated with dextran beads as taught by '055 is hemostatic or not is a property of the composition whether it is recognized by the inventors thereof or not. Applicant has not demonstrated unexpected properties for the composition as claim designated to patentably distinguish it over the references.

As to the art cited for secondary considerations, it is apparent that these references are directed to a method of using the composition for hemostasis rather than to the composition per se, as claimed. Therefore, these arguments fail to persuade.



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Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

The newly presented grounds of rejection based on obviousness-type double patenting will not preclude the finality of this Office action. Indeed, these grounds of rejection involve conflicting claims in a copending application newly discovered by the Examiner, which has inventor(s) with the present application, and applicants did not call the attention of the Office to this application. Applicants will not be permitted to extend the prosecution of the present application by reason of their inaction with regard to notice to the Office of conflicting claims in a copending application, the discovery of which necessitated the new grounds of rejection at this advanced point in the prosecution. Indeed, with appropriate notice, these grounds of rejection clearly could have been incorporated in a prior Office action. This situation is clearly analogous to the policy of making an action final where Applicant's material amendments to the claims necessitated a new ground of rejection, since in both instances it is applicant who caused the rejection to be applied after the case had received an action on the merits. See MPEP section 706.07(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

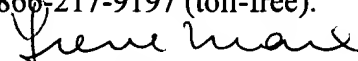
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx

Primary Examiner

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